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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,577	12/27/2004	Joseph W. Villard	6100-009	5236

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EXAMINER	
BOR, HELENE CATHERINE	

ART UNIT	PAPER NUMBER
3768	

NOTIFICATION DATE	DELIVERY MODE
06/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

scotugno@biopatentlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/500,577	VILLARD ET AL.	
	Examiner	Art Unit	
	HELENE BOR	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 57-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31 and 57-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/15/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Acknowledgement of Election/Restriction

2. The Examiner acknowledges the election of Group I drawn to a blood substitute/hemoglobin with traverse. The Examiner notes that the Applicant cancelled Claims 32-56 without prejudice to their right to file divisional application directed to the subject matter of those claims.

Claim Rejections - 35 USC § 102

3. Claim 1, 22, 63-71 & 79-81 are rejected under 35 U.S.C. 102(b) as being anticipated by Loeb (US Patent No. 4,448,188).

Claim 1, 79-81: Loeb teaches a method for performing optical imaging [fiberoptic viewing system for sending a monochromatic light beam] (Col. 8, Line 47-54) or light-based treatment [laser irradiation of the surface of the blood vessel for the removal of a plaque deposit] (Col. 3, Line 17-19) of at least a first tissue in an animal [blood vessel] (Abstract). Loeb teaches providing into the blood associated with first tissue a biologically effective amount of a low-scattering, oxygen-carrying blood substitute [substantially clear oxygen-bearing liquid] (Col. 4, Line 26-35). Loeb teaches wherein the low-scattering, oxygen-carrying blood substitute is selected to substantially reduce optical scattering [permit viewing with the blood vessel or use of the laser] (Col. 4, Line 22-25) from the blood fraction whilst substantially maintaining tissue oxygenation (Col.

3, Line 48-55). Loeb teaches applying an optical imaging or light-based treatment step to said at least a first tissue (Col. 3, Line 10-19).

Claim 22: Loeb teaches a blood substitute wherein the largest species in said solution in a size of about 6 nanometers (Col.5, Line 61-63 & Col. 6, Line 27-30).

Claim 63-71: Leob teaches the tissue being cardiac or any blood vessel in the body (Col. 3, Line 31-34). Loeb teaches treating blood vessels with plaque deposit (Col. 3, Line 18-19).

Claim Rejections - 35 USC § 103

4. Claim 2-21, 23-31, 57-62, 72-74 & 76-78 rejected under 35 U.S.C. 103(a) as being unpatentable over Loeb (US Patent No. 4,448,188) as applied to claim 1, 22, 63-71 & 79-81 above, and further in view of Rameshraja et al. (Rameshraja Palaparthy, Huashan Wang, Anil Gulati, Current aspects in pharmacology of modified hemoglobins, Advanced Drug Delivery Reviews. Volume 40, Issue 3, Blood Substitutes, 28 February 2000, Pages 185-198).

Claim 2-5: Loeb teaches the hemoglobin solution contained human hemoglobin (Col. 4, Line 54) and teaches using perfluorocarbons as a blood substitute, but fails to teach a blood substitute with modified hemoglobins (Col. 5, Line 13-33). However, Rameshraja teaches that two types of blood substitutes are in advance stages of development: perfluorocarbons (PFC) and modified hemoglobins. Rameshraja teaches PFCs have disadvantages such as inherent immunological response and higher risk to develop infection (Page 186, 1. Introduction) and many new developments regarding modified hemoglobin have been done to improve its physiological properties.

Rameshraja teaches a blood substitute which comprises human hemoglobin (Page 193, Part 2.7). Rameshraja teaches a blood substitute which is substantially non-particulate, acellular, bovine hemoglobin solution [Oxyglobin®] (Page 187, Part 2 & Page 192, Part 2.6) which allows for improved oxygen metabolism at the cellular level (Page 192, 2.6). It would have been obvious to one of ordinary skill in the art to substitute the blood substitute of Loeb with the Oxyglobin® as taught by Rameshraja in order to have improved oxygen metabolism at the cellular level (Page 192, 2.6)

Claim 6: Rameshraja teaches a blood substitute which is recombinantly produced (Page 188, Part 2.2).

Claim 7: Rameshraja teaches a blood substitute which is crosslinked (Page 190, Part 2.4).

Claim 8: Rameshraja teaches a blood substitute which is polymerized (Page 190, Part 2.4).

Claim 9: Rameshraja teaches a blood substitute which is glutaraldhyde crosslinked polymerized (Page 193, Part 2.7).

Claim 10: Rameshraja teaches a blood substitute which is surface modified (Page 189, Part 2.3).

Claim 11-21 & 31: Rameshraja teaches using blood substitutes to replace whole blood or red blood cells [near-complete blood replacement study; 0.7%] (Page 192, Part 2.6).

Claim 23-30: Loeb teaches the blood substitute to be substainally clear to allow for optical viewing or use of a laser. Also Loeb teaches a method for maximizing for the desired transparency to a particular laser wavelength (Col. 4, Line 43-46). Rameshraja

teaches using a blood substitute [Oxyglobin®] with physical properties (Page 192, Part 2.6) that are inherent to the blood substitute as disclosed with the Applicant's Specification (Page 24-25).

Claim 57-62 & 72: Loeb teaches a method for use in any blood vessel in the body but fails to specifically mention other body parts beside the coronary artery, however, Rameshraja teaches the tissue being brain, GIT, kidneys, mesentery, pancreas, skin and musculoskeletal (Page 187, Part 2.1). Rameshraja teaches using animal for applying the treatment (Abstract, Page 185 Part I & Page 192 Part 2.6). It is inherent that an animal would be "at risk" to any number of disorders throughout its existence and certainly any animal would be at risk for a vascularized tumor (Page 190, Part 2.3).

Claim 73-74: Rameshraja teaches using an animal that is a mouse [rat/murine] or human (Page 188, Part 2.1 & Page 190, Part 2.4).

Claim 76-78: In implementing the blood substitute [Oxyglobin®] as disclosed above, one must obtain a Material Safety Data Sheet (BioPure MSDS; enclosed herein) as required by 20 CFR 1910.1200 Hazard Communication Standard to package the blood substitute with a MSDS as a kit. By OSHA regulation, MSDS sheet are available electronically online and available via hard copy within the work space the product is being used. Applicant is reminded that the details of the claimed "instructions" in a kit cannot serve to distinguish over a kit having the same elements and different printed "instructions".

5. Claim 75 & 82 rejected under 35 U.S.C. 103(a) as being unpatentable over Loeb (US Patent No. 4,448,188) as applied to claims 1, 22, 63-71 & 79-81 above, and further in view of Swanson et al. (US Patent No. 5,321,501).

Claim 75 & 82: Loeb teaches a method for performing optical imaging [fiberoptic viewing system for sending a monochromatic light beam] (Col. 8, Line 47-54) or light-based treatment [laser irradiation of the surface of the blood vessel for the removal of a plaque deposit] (Col. 3, Line 17-19) of at least a first tissue in an animal [blood vessel] (Abstract). Loeb teaches providing into the blood associated with first tissue a biologically effective amount of a low-scattering, oxygen-carrying blood substitute [substantially clear oxygen-bearing liquid]. Loeb teaches wherein the low-scattering, oxygen-carrying blood substitute is selected to substantially reduce optical scattering [permit viewing with the blood vessel or use of the laser] (Col. 4, Line 22-25) from the blood fraction whilst substantially maintaining tissue oxygenation (Col. 3, Line 48-55). Loeb teaches applying an optical imaging or light-based treatment step to said at least a first tissue (Col. 3, Line 10-19). Loeb teaches using a fiberoptic viewing system (Col. 8, Line 46-54) but fails to teach optical coherence tomography. However, Swanson teaches optical coherence tomography (Figure 1B & Claim 2) for producing cross-sectional images (Col. 4, Line 59-63) with sharp focus and sensitivity (Col. 2, Line 24-33). It would have been obvious to one of ordinary skill in the art to modify the method of Loeb to include the optical coherence tomography imaging as taught by Swanson in order to produce cross-sectional images (Col. 4, Line 59-63) with sharp focus and sensitivity (Col. 2, Line 24-33).

Response to Amendment

6. The Declaration under 37 CFR 1.132 filed 02/17/2009 is sufficient to overcome the rejection of claims 1-4, 7-9, 11-31, 75 & 79-82 based upon Villard'2001.

Response to Arguments

7. Applicant's arguments, see Page 8, filed 02/17/2009, with respect to 35 USC § 112, second paragraph have been fully considered and are persuasive. The rejection of Claim 20 has been withdrawn.

Applicant's arguments, see Page 9, filed 02/17/2009, with respect to the rejection(s) of claim(s) 1-31, 57-63, 65-74 & 76-78 under 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Loeb (US Patent No. 4,448,188), Swanson et al. (US Patent No. 5,321,501) and Rameshraja et al. (Rameshraja Palaparthy, Huashan Wang, Anil Gulati, Current aspects in pharmacology of modified hemoglobins, Advanced Drug Delivery Reviews. Volume 40, Issue 3, Blood Substitutes, 28 February 2000, Pages 185-198). Although a new rejection as been applied, any relevant arguments will still be addressed. The Applicant submitted arguments stating, "Examiner has not provided any rational or technical reasoning why Oxyglobin® could have inherent properties of 'biologically effective amount of a low-scattering, oxygen-carrying blood substitute, wherein the low-scattering, oxygen-carrying blood substitute is selected to substantially reduce optical scattering from the blood fraction whilst substantially maintaining tissue oxygenation'..." (Page 9). The Examiner respectfully disagrees. While Applicant directs claims to certain observable

properties when low-scattering, blood substitute is infused into the patient in the manner disclosed, the measured properties as claimed are inherent results. Applicant's description on page 29 gives evidence to the inherent properties. Applicant is remained that the case law on inherency is well established. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). Products of identical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELENE BOR whose telephone number is (571)272-2947. The examiner can normally be reached on M-T 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. B./
Examiner, Art Unit 3768

/Eric F Winakur/
Primary Examiner, Art Unit 3768